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Douglas E. Erickson
Douglas E. Erickson

29,530
Reg. No.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant	:	T. Douglas Mast.
Serial No.	:	10/721,034
Filed	:	November 24, 2003
Title	:	METHOD FOR MONITORING OF MEDICAL TREATMENT USING PULSE-ECHO ULTRASOUND
Docket	:	END5042USCIP
Examiner	:	Francis J. Jaworski
Art Unit	:	~~3737~~ 3768 DEE 5/14/07

Commissioner for Patents
P.O. Box 14350
Alexandria, VA 22313-1450

Sir:

DECLARATION OF FOSTER B. STULEN UNDER 37 CFR 1.132

I, Foster B. Stulen, declare and state the following:

1. For the last 6 years I have been employed by Ethicon Endo-Surgery, Inc., the assignee of the above-identified patent application. I have worked for Ethicon as a Principal Engineer. My technical work over the last 26 years has been concentrated in the field of ultrasound including ultrasound imaging.

2. I received a B.S. degree in Mechanical Engineering from Rensselaer Polytechnic Institute in 1973. I received an SM. degree in Mechanical Engineering in 1975 and a Ph.D. in Mechanical Engineering in 1980 both from Massachusetts Institute of Technology.

3. I have read the above-identified patent application including the claims as amended. I have read the Office Action of February 13, 2007 for the above-identified patent application. I have read the Okazaki (US 5,005,580) and Lizzi (US 6,533,726) patents cited in the office action. I have also reviewed Attachment A of the Amendment After Final which is a graph of sin(x), cos(x) and sin(x) – cos(x).

4. The independent claims 1, 13, 16, 25 and 30 require subtracting a second time-varying signal (or imaging signals of a second image frame or of a second set of image frames) from a first time-varying signal (or imaging signals of a first image frame or of a first set of image frames) to derive a time-varying difference signal (or a set of time-varying difference signals). The Okazaki and Lizzi patents, taken alone or in combination, do not teach, suggest or describe this.

5. Two items are key to understanding the difference between the claims and the Okazaki and Lizzi patents. One is to understand that two time-varying signals from the same location are being subtracted in the claims whereas two signal-amplitude-dependent image pixel values from the same location in two images are being subtracted in the Okazaki and Lizzi patents. The other is to understand that the term "amplitude" as used in the Okazaki and Lizzi patents means a number, such as a peak amplitude or an average amplitude, which is time-invariant (fixed) for a particular time-varying signal (but which can change for the next time-varying signal).

6. The Okazaki and Lizzi patents each: determine a first time-invariant amplitude value (such as a maximum amplitude value from a normal or equilibrium value taken as zero or an RMS [root-mean-square] average amplitude value, etc) of the first time-varying signal; then determine a second time-invariant amplitude value of the second time-varying signal; and then subtract the second time-invariant amplitude value from the first time-invariant amplitude value to derive a time-invariant number (for that particular pair of time-varying signals), wherein the time-invariant number is used to determine a gradation value of a pixel of a location in an image and wherein the pixel gradation value is a fixed value until new signals are received and processed.

The subtraction in the claims yields a time-varying signal whereas the subtraction in the Okazaki and Lizzi patents yields a fixed (time-invariant) number.

7. Okazaki discloses subtraction of the amplitude of two signals. Okazaki teaches detecting the amplitude of the signals (see column 3, lines 22-25) which a signal converting system outputs as tomogram data to an image memory (see column 3, lines 39-41), and a subtraction image is formed from the stored tomogram data (see column 3, lines 41-44). Tomogram data is fixed amplitude data from particular signals (which can change for later signals). Okazaki teaches that a pixel gradation value for a location (see the particular level of gradation lightness or darkness for a particular pixel location in Okazaki's figure 4C) is derived by subtracting a fixed amplitude value of a same-particular-location-reflected time-varying second signal during treatment (see the particular level of gradation lightness or darkness for a same particular pixel location in Okazaki's figure 4B) from a fixed amplitude value of a same-particular-location-reflected time-varying first signal (see the particular level of gradation lightness or darkness for a same particular pixel location in Okazaki's figure 4A) before treatment.

8. Lizzi teaches subtraction of image scans (see Lizzi's blocks 340 and 345) which, for a particular pixel location in an image scan, are subtractions of fixed amplitude values of signals identical to the teaching of Okazaki. Subtraction of image scans is subtraction of images (see the Abstract of Lizzi) which is the subtraction of signal-amplitude-dependent pixel values.

9. The subtraction in Okazaki and/or Lizzi is derived from the time-invariant amplitude values of a particular before-treatment signal (i.e., a first signal) and a particular during-treatment signal (i.e., a second signal) and is a fixed number and is not a time-varying difference signal. A different fixed number for Okazaki and/or Lizzi can be derived by subtracting the time-invariant amplitude values of an additional new third signal and the previous second signal or by subtracting the time-invariant amplitude values of additional new third and fourth signals. However, subtracting fixed amplitude values of third and second signals or fixed amplitude values of third and fourth signals to derive a different fixed number from the fixed number derived by subtracting fixed amplitude values of first and second signals is not subtracting a

time-varying second signal from a time-varying first signal to derive a time-varying difference signal.

10. A question might be raised whether the difference in time-invariant amplitude values of two time-varying signals is the same as a time-invariant amplitude value of the difference of two time-varying signals. The answer is no. For example, consider a time-varying sine wave signal [y1=sin(x) where x is time] having a fixed amplitude value of one and a time-varying cosine wave signal [y2=cos(x)] having a fixed amplitude value of one. The difference in the fixed amplitude values of the two signals is zero. However, subtracting the cosine wave signal from the sine wave signal results in a signal [y3=sin(x)-cos(x)] which has a fixed amplitude value of about 1.4 which is not a fixed amplitude value of zero. It is noted that Attachment A of the Amendment After Final was a graph of sin(x), cos(x) and sin(x) – cos(x).

11. A basic mathematical statement can summarize the key difference between the prior work and this application: " the absolute value of a difference does **not equal** the difference of the absolute values". Referring to Equation 1 in the application, the absolute value (or magnitude) of the difference of signals p_o and p_1 is taken first, then the absolute value (magnitude) as denoted by $|p_o-p_1|$. Because the prior art uses B-scans or complete image scans, the absolute values have already been taken before the subtraction. In essence their difference is $|p_o|-|p_1|$. It is well known in the field of signal processing that feature and information extraction are best performed on the varying wave forms than on signal magnitudes.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements and the like so made are punishable by fine or imprisonment or both under Section 101 of Title 18 of the United Stated Code, and that such willful false statements may jeopardize the validity of the above-identified patent application and any patent issuing thereon.

Date: 5/9/07 Foster B Stulen

Foster B. Stulen

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